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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/669,418

Applicant(s)

DULEBOHN ET AL.

Examiner

Chih-Min Kam

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-11 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-5, 8-11 and 13 are pending.

Applicants' amendment filed on January 24, 2002 (Paper No. 6) is acknowledged, and applicant's response has been fully considered. Claims 1, 8, 9, 10 and 11 have been amended, and claims 6, 7 and 12 have been cancelled.

### **Objection Withdrawn**

2. The previous objection of disclosure regarding the terms "lysine:mg:malic:citric", "1.49:1.2.16:0.72" and "lysine:ca:malic:citric", is withdrawn in view of applicants' amendment to the specification at page 5.

### **Rejection Withdrawn**

#### ***Claim Rejections – 35 USC § 112, second paragraph***

3. The previous rejection of claims 1-8, 10 and 12-13 under 35 USC § 112, second paragraph regarding the terms "the composition added in an amount sufficient to reduce photooxidation relative to.....the anti-oxidation composition", "0.001% and 2%" "lysine:mg:malic:citric", "1.49:1.2.16:0.72" and "lysine:ca:malic:citric", is withdrawn in view of applicants' amendment to the claims, cancellation of claims 16 and 18-21, and applicants' response at page 4 in Paper No. 6.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-5, 8-11 and 13 are rejected under 35 U.S.C. 112, first paragraph.

Claims 1-5, 8-11 and 13 are rejected because the specification, while being enabling for a method of reducing photooxidation or air oxidation in a food product comprising the step of dispersing within the product an antioxidation composition comprising an amino acid of lysine or aspartic acid, a metal ion of CaO, MgO and/or ZnO, and a carboxylic acid of malic acid, citric acid or succinic acid, does not reasonably provide enablement for a method of reducing photooxidation or air oxidation in a food product comprising the step of dispersing within the product an antioxidation composition comprising any amino acid, any metal ion, and any organic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-5, 8-11 and 13 are drawn to a method of reducing photooxidation or air oxidation in a food product comprising the step of dispersing an antioxidation composition comprising an amino acid, a metal ion, and an organic acid (claims 1-5), in a product of milk (claims 8 and 9), in a product of white chocolate (claims 10 and 11) or in a product of plastic (claim 13). The specification, however, only discloses cursory conclusions (page 1, line 18-page 2, line 5; page 2, line 21-page 4, line 2) without data supporting the findings, which state that a method of reducing photooxidation or air oxidation in a food product comprising the step of dispersing an antioxidation composition comprising an amino acid, a metal ion, and an organic acid. There are no indicia that the present application enables the full scope in view of the method for as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled. The factors considered in

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determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses unspecified variants regarding the identity and the amount of amino acid, metal ion, and carboxylic acid in the antioxidation composition, which are not adequately described or demonstrated in the specification.

(2). The absence of working examples:

There are no working examples indicating the claimed methods in association with the variants except for the composition comprising lysine or aspartic acid, MgO, CaO, and/or ZnO, and malic acid and/citric acid.

(3). The state of the prior art and relative skill of those in the art:

The general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the ratio of various components in the composition to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass a method of reducing photooxidation or air oxidation in a food product comprising the step of dispersing an antioxidation composition comprising an amino acid, a metal ion, and an organic acid. However, the specification does not adequately describe

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the ratio of various components in the composition, it is unpredictable whether the composition comprising various components would produce the effect of antioxidation in a food product.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method of reducing photooxidation or air oxidation in a food product comprising the step of dispersing an antioxidation composition comprising an amino acid, a metal ion, and an organic acid. However, the specification has only demonstrated a composition containing lysine or aspartic acid, MgO, CaO or/and ZnO, and malic acid, citric acid or succinic acid at a specific ratio being used for reducing photooxidation in a food product, there is no composition containing other amino acids, metal ions, and carboxylic acids being described. Moreover, there are no working examples of using these variants in the claimed method for reducing photooxidation. Since the specification does not provide any specific guidance on the ratio of various components in the composition, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of different compositions comprising various components used in the claimed method.

(6). Nature of the Invention

The scope of the claims includes a method of reducing photooxidation in a food product using the antioxidation composition, but the specification does not provide sufficient guidance regarding the components of the composition in the claimed method. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, while the working example does not demonstrate the claimed variants, and the guidance and the teaching in the specification are

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limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various compositions in the claimed method.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5, 8-11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 8-11 and 13 are indefinite because the claims lack essential steps in the method of reducing photooxidation or air oxidation in a food product. The omitted step is the outcome of the process. Claims 2-5, 8-11 and 13 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

6. Claims 1-5, 8-11 and 13 are indefinite because of the use of the term "at least one amino acid, at least one metal ion and at least one organic acid". The term "at least one amino acid, at least one metal ion and at least one organic acid" renders the claim indefinite, it is unclear in the claim how many amino acids, metal ions and organic acids are intended in the composition, and what amino acid, metal ion and organic acid are in the composition. Claims 2-5, 8-11 and 13 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

7. Claim 9, for example, recites the limitation "the range" in lines 1-2, and "magnesium" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites

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"metal ion" in the antioxidation composition, however, claim 9 recites "magnesium" which is considered as magnesium element not magnesium ion. See also claim 11.

8. Claim 13 is indefinite because the claim depends from a cancelled claim, claim 12.

***Conclusion***

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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April 23, 2002

*Christopher S. F. Low*  
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